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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,990	01/21/2004	Ashok Vinayak Purandare	LD0325 NP	4293

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,990	PURANDARE ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/12/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Claims 1-10 are presented for prosecution on the merits.

Claim Rejection(s)—35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for lung carcinoma, does not reasonably provide enablement for all types of cancer embraced by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The claims are drawn to a method of treating cancer in a mammal in need thereof comprising administering to the mammal an effective amount of the Formulae (I) or (III) alone

or in combination with at least one other anti-cancer agent.

(2) The state of the prior art

With respect to cancer, this a broad term which encompasses numerous forms of neoplastic diseases, each involving different types of tissues and organs and also includes blood-borne diseases. As recognized in the art, many different anti-neoplastic drugs are used to treat a variety of cancers, but there is no one drug or one drug combination, which is capable of treating all cancers in general. Please see pages 1226-1229 of Goodman & Gilman's.

Additionally, the prior art does not recognize the complete prevention of cancer.

(3) The relative skill of those in the art

The relative skill of those in the art is high. However, given the state of the art as set forth above, the artisan is currently unaware of any one particular anticancer agent or combination of agents that is effective against all cancer cell types. Furthermore, the burden of enabling the prevention of cancer would be much greater than that of enabling the treatment of cancer for the purpose of inhibiting further development or causing the regression of any given type of cancer.

(4) The predictability or unpredictability of the art

The unpredictability of the pharmaceutical and cancer art is high. Additionally, the lack of significant guidance from the present specification or prior art with regard to the actual treatment and prevention of all cancer cell types in a mammal, including a human, with the claimed compound(s) as the active ingredient(s) makes practicing the claimed method unpredictable.

(5) The breadth of the claims

The complex nature of the subject matter to which the present claims are directed is

exacerbated by the breadth of the claim. The claims are broad and encompass treatment of a vast number of possible cancer types including solid tumors as well as blood-borne tumors.

Additionally, the claims are drawn to "treatment" of cancer wherein the term "treatment" has been defined by applicant to include "prevention" of "cancer" in an individual which may be predisposed to cancer but is not yet suffering from it (please see the specification page 36, lines 17-22).

Finally, to the extent that the term "treatment" indicates inhibiting further development or causing the regression of a disease, i.e. cancer, such is not enabled for the breadth of the claims, which encompass all cancers in general.

(6) The amount of direction or guidance presented

Applicant's specification appears to only be enabled for the treatment of lung carcinoma. It does not enable one of ordinary skill in the art to use the claimed invention in the treatment of the numerous neoplastic diseases covered by the term "cancer." Applicant's specification does not set forth a representative number of examples of cancers, which would be treated by the claimed compound or combination of compounds.

Moreover, the specification does not provide guidance as to how one of ordinary skill in the art would accomplish the objective of preventing cancer, including lung carcinoma, in a patient or how a patient could be kept from even being susceptible to cancer. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active agent(s) for preventing cancer.

(7) The presence or absence of working examples

The working examples in the specification describe studies of the compounds of the

invention in inhibiting proteasomes in as well as inhibitory activity against human lung carcinoma cells. Please see pages 99-100.

(8) The quantity of experimentation necessary

Since (1) the prior art recognizes that no one compound or combination of compounds is capable of treating the vast number of possible cancerous diseases encompassed by the term "cancer"; (2) the prior art does not recognize the complete prevention of cancer; (3) the specification shows activity against only one type of cancer, i.e. lung carcinoma, and (4) since the claims are very broad and include treatment of any type of cancer ranging from solid cancers to blood-borne cancers, one of ordinary skill in the art would be burdened with undue experimentation to determine which cancers would be treated by administration of the claimed compound(s).

Additionally, it is highly unlikely, and the Office would require experimental evidence to support the contention, that the claimed compound or combination of compounds could actually prevent cancer, including lung carcinoma, by simply administering, by any method, an amount of the claimed compound(s). The specification fails to enable one of ordinary skill in the art to practice the prevention of cancer.

Finally, the term "prevention" is synonymous with the term "curing" and both circumscribe methods of absolute success. Since absolute success is not reasonably possible with most diseases/disorders, especially those having etiologies and pathophysiological manifestations as complex/poorly understood as cancer, the specification, which lacks an objective showing that any cancer can actually be prevented or cured, is viewed as lacking an adequate written description of the same.

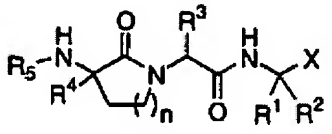
Claim Rejection(s)—35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/07407 ('407).

WO '407 disclose a pharmaceutical composition containing a pharmaceutically acceptable carrier and a compound of Formula (I):



(I)

wherein n, R^1, R^2, R^3, R^4, R^5, and X are defined below,

at pages 5-9. WO '407 also discloses a method of treating HCV infection in a host, wherein the method comprises administering to the host a therapeutically effective amount of a compound of Formula (I) or a pharmaceutically acceptable salt thereof. Please see page 26.

Claims 8-9 are anticipated by WO '407 because WO '407 discloses administering an identical active agent, i.e. a compound of formula (I), to a host in need thereof. Accordingly, inhibition of a proteasome would be inherent.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v.*

Eagle Mfg. Co., 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 1 and 10 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 27, 35 of copending Application No. 10/010,184. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-34, 36-42 of copending Application No. 10/010,184. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428. 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting

claims are not identical, they are not patentably distinct from each other because the claims of the instant application are generic to all that is recited in the claims of USAN '184. That is, the claims of USAN '184 fall entirely within the scope of the claims of the instant application. In other words, the claims of the instant application are anticipated by claims 28-34, 36-42 of USAN '184. Specifically, the claims of USAN '184 recite species and sub-generic structures embraced by the claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-10 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
Oct. 2, 2005

Cybille Delacroix-Muirheid
Patent Examiner Group 1600